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#### The UK Life Sciences sector is at a turning point. Now is the time to commit to its future

A White Paper from BritishAmerican Business, in partnership with MSD

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# Introduction

The UK has the talent, science base, and health care infrastructure to become a life sciences superpower and businesses are committed to realising this opportunity. However, with a decline in clinical trial activity and an increasingly unfavourable commercial environment, the country is now at an inflection point, risking its competitive advantage in life sciences as other countries eager to grow their share of the global life sciences industry vie for future investment.

As successive governments in the UK have recognised, life sciences are key to both better health outcomes and economic growth. The Covid-19 pandemic demonstrated the importance of the sector in addressing current and future health challenges, as well as the ability of industry, regulators, and government to quickly bring new, innovative treatments to patients across the UK. The sector is also major contributor to the British economy and has been successful in attracting foreign direct investment, including from many leading American life sciences firms.<sup>1</sup>

Although the UK has longstanding strengths in life sciences, there is recognition from both government and industry that areas such as commercial clinical trials or medicines manufacturing capacity have declined in recent years amongst other worrying trends reflected in the UK's life sciences competitiveness indicators.<sup>2</sup> The consensus from business is that tangible action is needed from government to maintain a competitive commercial environment, attract foreign investment, and achieve the UK's ambition to become a science superpower by 2030.<sup>3</sup>

This white paper outlines a forward-looking set of recommendations for a stronger policy and regulatory life sciences policy ecosystem in the UK that will support and sustain the UK's position as a leading actor in the field; attract investment from transatlantic companies; and help people access medicines, prevent disease, and live longer, healthier lives.

The paper builds on the BritishAmerican Business Policy Agenda, which identifies 'life sciences' as a priority for transatlantic businesses, as well as an industry-specific roundtable discussion convened by BritishAmerican Business, organised in partnership with MSD, on January 17, 2023, in London.<sup>4</sup>

# **State of Play**

The UK is a world leader in life sciences investment, research, and innovation. A strong skill base, unified health system, and continuing investment in research have helped to support a thriving life science industry that contributes billions to the country's economy. The UK is also home to two of the top five universities globally in life sciences teaching, offering a strong foundation for commercial research and innovation.

Life sciences support almost a quarter of a million jobs in the UK and generated approximately £89 billion in economic value in 2020.<sup>5</sup> Inward life sciences foreign direct investment in the UK was £1.9 billion in 2021, with US companies contributing a significant share of it.<sup>6</sup> In fact, US commercial R&D spend is growing faster than any other country in the world, and attracting an extra 1% of US biopharmaceutical R&D would boost UK investment by nearly £800 million per year.<sup>7</sup>

In recognition of the important role the sector plays in the British economy, the UK government has published a series of strategies to build on the UK's global leadership in life sciences, including the Life Sciences Industrial Strategy, Life Sciences Vision, and the Board of Trade's Life Sciences Report published in November 2022.

The success of the vaccines programme during the pandemic showed that the life sciences sector is capable of quick and important innovation when the right systems are put in place, and a focus on the cross-cutting themes outlined in each of these strategies – creating an attractive environment for inward investment, enhancing R&D capabilities, developing the NHS's role as a research partner, and building on a strong regulatory system – will contribute to the future success of UK life sciences innovation.



While there is both the opportunity and need for life sciences investment in the UK, the industry faces real challenges, particularly related to the commercial environment, clinical trials, and the regulatory ecosystem. For example, pharmaceutical companies in the UK are subject to a commercially unsustainable medicine pricing scheme in 2023, with rebate rates currently set at 26.5% of revenue—a significant increase from previous years.<sup>8</sup> Commercial clinical trial activity, meanwhile, has significantly decreased and UK investment in R&D has declined relative to other comparator countries.<sup>9</sup>

With planned negotiations for a successor scheme to the Voluntary Pricing and Access Scheme (VPAS) this year, 2023 is a critical moment for the UK to take action to remain an internationally competitive destination for life sciences investment. The commercial and operating environment will inevitably have an impact on companies' decisions regarding future investment and there is fierce competition from countries around the world who have similar ambitions to lead in the development of new, innovative medicines and treatments.

In this context, transatlantic business has called on the UK government to realise the ambitions of its Life Sciences Vision and the 2023 Science and Technology Framework and build upon its position as a leading life sciences hub to remain globally competitive.

The UK's position outside the EU provides a new opportunity to establish an independent trade policy, streamline regulatory processes, and build a competitive commercial environment. Through ongoing discussion with government and relevant trade bodies, such as BritishAmerican Business, the transatlantic life sciences community has expressed its readiness to work with government to capitalise on this opportunity and build a thriving life sciences ecosystem in the UK.

### **Recommendations to Policy Makers**

Building on BAB's 2022-2023 Policy Agenda, the following sections identify three areas of focus: the commercial environment, clinical trials, and trade and intellectual property. Our recommendations reflect the priorities of leading British and American life sciences companies, and the constructive conversation had between industry and government stakeholders in a life sciences roundtable convened by BAB in January 2023.

We welcome the government's support for the sector and openness to dialogue, particularly at such a critical moment for life sciences in the UK. Ongoing partnership with industry will be key to unlocking the potential of life sciences, delivering economic growth across the UK, and tackling present and future health challenges.



Factors such as a country's skill base and educational institutions, research and manufacturing capabilities, and access to global supply chains are all fundamental pieces of a thriving commercial environment and drivers of inward investment. The UK has historically attracted many international firms, including from the US, and is home to many successful, homegrown British life sciences companies – in large part due to its strengths in these areas.

As a result, the life sciences sector has continued to invest in the UK economy, with an estimated  $\pm 1.9$  billion in life sciences foreign direct investment in the UK in 2021.<sup>10</sup> It is this continuing investment that has made the UK a world leader in life sciences and that will help it become a life sciences superpower in the next decade.

However, there are real challenges to achieving this goal, as the UK seeks to compete with other countries for future investment. A notable challenge is the UK's Voluntary Scheme for Branded Medicines Pricing and Access (VPAS), a five-year negotiated scheme between government and industry that will require companies operating in the UK to pay 26.5% of sales revenue as a rebate in 2023 – a payment rate that if left unchanged, will become financially unsustainable for industry and leave the UK an outlier compared to other markets. Schemes in comparable countries across Europe have set considerably lower rebate rates: Germany has a general rebate of 12%, Spain at 7.5%, and Ireland at 7.75%.

To ensure that the UK remains a globally competitive destination for life sciences innovation and investment—one of the four guiding themes of the Life Sciences Vision—it is important that policymakers

review the commercial environment as a whole to ensure reimbursement, tax, available workforce, and other investment determinants support UK innovation and growth.

- We urge government, industry, and the NHS to work together to achieve a successor voluntary pricing scheme which achieves meaningful progress in four areas: restoring an internationally competitive commercial environment for life sciences; supporting UK clinical research and R&D; ensuring rapid patient access and uptake of new medicines; and improving population health and productivity through health innovation
- We welcome the announcement in the 2023 Spring Budget regarding full expensing and incentives for R&D, but caution against fiscal measures that will have a negative impact on innovation and investment. The UK must preserve a globally competitive corporate tax environment in which capital expenditure by companies is fully recognised as a contribution to the economy, and the announced six-point rise in corporation tax sends a discouraging signal to investors.
- To ensure companies have the talent they need, we encourage continued government investment in the workforce, including incentives for skills training and upskilling programs as well as shortening visa processing times for skilled workers in the life sciences sector.
- Small and medium-sized enterprises are important contributors to the UK life sciences ecosystem. The UK should provide continuing support to help these companies scale in the UK through access to finance or targeted investment, and we welcome the announcement of additional tax relief for R&D intensive SMEs in the 2023 Spring Budget.



Commercial clinical trials are an essential step in developing new medicines, treatments, and vaccines. They also provide value to the NHS, job market, and wider UK economy; commercial clinical research generated an estimated £355 million for NHS England between 2018 and 2019.<sup>11</sup>

The UK has longstanding strengths in clinical research and is consistently ranked as a leading destination for new trials. The UK's response to the pandemic highlighted these strengths—in 2020 the UK initiated 68 commercial Covid-19 clinical trials, placing it among the top three initiators of Covid-19 trials globally.<sup>12</sup>

However, the past few years have seen a worrying overall decline in the number of commercial clinical trials initiated in the UK. Between 2017 and 2021, the number of industry commercial trials fell 41%. Slow set up and regulatory approval timelines are one factor driving this decline, as average approval times have increased from 25 to upwards of 247 days.<sup>13</sup> Anecdotal evidence from BAB's life sciences roundtable suggest timelines can often exceed this, stretching in excess of 400 days.

The UK also faces difficulty recruiting patients once trials are approved and has experienced a 44% decline in patient access to industry clinical trials between 2017/18 and 2021/22. Fewer than half of industry clinical trials are able to recruit their target number of participants, and on average, the UK treats fewer participants per industry trial than other comparator countries in Europe.<sup>14</sup>

The current challenges facing the UK commercial clinical trials ecosystem pose serious challenges for the UK's global competitiveness, as life science firms turn to other countries to initiate clinical trials. There are already indicators that companies are choosing other jurisdictions to set up research or clinical trial activity—the UK was ranked 4th in the world for Phase III industry clinical trials in 2017 but has since fallen to 10th.<sup>15</sup> This decline also has implications for UK patients, who will face diminishing access to innovative medicines or treatments.

Partnership with industry will be needed to address these issues and to rebuilding a strong clinical trials environment in the UK.

- Working closely alongside the life science sector, regulators and government should work at pace to
  reform the clinical trials ecosystem and ensure a shorter, streamlined set up and approvals process. We
  welcome the additional funding granted to the MHRA at the Spring 2023 budget to fast-track patient
  access to cutting-edge medicinal products and hope that the extra resource will be used to ease current
  capacity issues in the clinical trials approvals process, as well as at other stages of the licensing process.<sup>16</sup>
- NHS England's recently published research guidance (underpinning the Health & Care Act 2022) is a
  welcome step in the right direction; however, more must be done to address the research culture within
  the NHS. How the NHS views research needs to change; this must be viewed as a benefit and something
  that must be done as per the mandate, as opposed to additional work, to avoid working almost in a
  voluntary system. If research is properly resourced and written into job plans and into the structure of
  the trust, this would signal its importance and can help change the culture. Clinical trials are an essential
  part of the entire life sciences ecosystem, bringing benefits to patients, the NHS and the economy, and
  crucially can improve the standard of care for patients. A cultural shift is urgently needed to realise these
  benefits for the UK.



The UK government's international trade agenda presents an opportunity for life science firms to continue exporting UK innovations globally, while also accessing the talent and imports needed from abroad. The liberalisation of trade with likeminded partners can reduce regulatory barriers, encourage inward investment, and promote closer regulatory alignment - each an important step towards strengthening industry in the UK.

A strengthened economic partnership with the US, for example, presents significant opportunity for the transatlantic life science industry, particularly as medicinal and pharmaceutical products are one of the top UK goods exports to the US (approximately £6.7 billion in 2022).<sup>17</sup>

As part of its trade agenda, the UK also has an opportunity to drive global standards in areas like intellectual property (IP). The life sciences sector is highly dependent on strong IP frameworks to enable innovation and investment and has welcomed the UK government's continuing support for a high standard of IP protection both domestically and in multilateral institutions. In particular, there is cross-industry recognition and support of the UK's continued leadership in the WTO debate on a waiver to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) for Covid-19 vaccines.

In this context, we encourage the UK government to continue to work closely with industry to ensure its outward-facing trade agenda delivers for the domestic life sciences sector.

- We urge the UK to oppose any further expansion of the TRIPS waiver to include Covid-19 diagnostics and therapeutics. Dismantling the framework that brought solutions to tackle Covid-19 and facilitated an unprecedented number of partnerships, voluntary licensing, and knowledge sharing agreements could have ripple effects not only for future public health challenges, but for all sectors that invest in research and innovation.
- We welcome the UK's ambition to pursue a global trade agenda that delivers for industry and maintains a high standard of IP protection. An enhanced UK-Switzerland free trade agreement, for example, presents an opportunity for each country—both world leaders in science and innovation—to show leadership and an intent to set a global precedent for strong IP frameworks. We encourage the UK to continue to work with likeminded partners to strengthen global IP standards through trade policy.
- There is an opportunity for increased cooperation and coordination between the MHRA, DBT, OLS, and Department for Health and Social Care (DHSC) for a more unified approach to promoting the strength of the UK life sciences sector globally and in encouraging inward investment.
- In a transatlantic context, the US and UK should build upon progress made in the UK-US Trade Dialogues in Baltimore and Aberdeen to continue collaborating on supply chain resilience. Medicines and medical equipment should constitute a key part of ongoing discussions on critical supply chains.
- We encourage the UK and the US to continue talks around economic collaboration in life sciences, which should inform broader efforts to drive a global regulatory harmonization and US-UK leadership on intellectual property protection and enforcement.

### Conclusion

Today, the UK has the challenge and opportunity to take action to be a competitive environment for the life sciences industry. Tangible policies and practices need to be put in place supporting the strategies outlined in the UK Life Sciences vision, and industry stands ready to support these actions.

Delivering on these recommendations will ensure that the UK remains a globally competitive market for life sciences, which will lead to greater international collaboration and investment—particularly in a transatlantic context given the prominence of US life science companies and their desire to have a footprint in the UK.

Improving the commercial and clinical trials ecosystems will improve the business environment for life sciences firms, encourage economic growth, and deliver for patients across the UK.

## References

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<sup>3</sup> Department for Science, Innovation and Technology, <u>UK Science and Technology Framework</u>, March 2023

<sup>4</sup> BritishAmerican Business, <u>BAB-Policy-Agenda-2022-23.pdf (babinc.org)</u>, October 2022

<sup>5</sup>UK Board of Trade, Life Sciences: What's next for this top UK sector? November 2022

<sup>6</sup> Ibid.

<sup>7</sup>APG, Vision for Growth, October 2022

<sup>8</sup>Department for Health & Social Care, <u>The 2019 voluntary scheme for branded medicines pricing and</u> <u>access</u>, December 2022

<sup>9</sup> ABPI, <u>Rescuing patient access to industry clinical trials in the UK</u>, October 2022; Office for Life Sciences, <u>Life science competitiveness indicators 2022</u>, July 2022; Office for Life Sciences, <u>Life science competitiveness indicators 2021</u>, July 2021

<sup>10</sup> UK Board of Trade, Life Sciences: What's next for this top UK sector? November 2022

<sup>11</sup> ABPI, <u>Clinical research in the UK: and opportunity for growth</u>, September 2021

<sup>12</sup> Ibid.

<sup>13</sup> ABPI, <u>Rescuing patient access to industry clinical trials in the UK</u>, October 2022 <sup>14</sup> Ibid.

<sup>15</sup> ABPI, <u>Rescuing patient access to industry clinical trials in the UK</u>, October 2022

<sup>16</sup> HM Treasury, <u>Spring Budget 2023</u>, March 2023

<sup>17</sup> DIT, <u>Trade and Investment Factsheet: United States</u>, February 2023



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